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**Antiviral Cellular Therapy for Enhancing T-cell Reconstitution Before or After Hematopoietic Stem Cell Transplantation (ACES)**

**Grant Award Details**

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Antiviral Cellular Therapy for Enhancing T-cell Reconstitution Before or After Hematopoietic Stem Cell Transplantation (ACES)

**Grant Type:** Clinical Trial Stage Projects

**Grant Number:** CLIN2-10392

**Investigator:**

<b>Name:</b>	Michael Pulsipher
<b>Institution:</b>	Children's Hospital of Los Angeles
<b>Type:</b>	PI

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**Disease Focus:** Blood Cancer, Blood Disorders, Bone Marrow Transplant and Viral Infection, Cancer

**Human Stem Cell Use:** Adult Stem Cell

**Award Value:** \$4,825,587

**Status:** Active

**Grant Application Details**

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**Application Title:** Antiviral Cellular Therapy for Enhancing T-cell Reconstitution Before or After Hematopoietic Stem Cell Transplantation (ACES)

**Public Abstract:****Therapeutic Candidate or Device**

Partially HLA-matched virus-specific T-cell therapy targeting cytomegalovirus, Epstein-Barr virus, and adenovirus.

**Indication**

This study will treat persistent viral infections with CMV, EBV, and/or adenovirus in patients with immunodeficiency.

**Therapeutic Mechanism**

The goal of this study is to use banked virus-specific T-cell therapy in A) patients who have persistent viral infections after bone marrow or cord blood transplant, and B) patients with primary immunodeficiency conditions who have persistent viral infections and have not undergone transplantation.

**Unmet Medical Need**

Viruses account for up to 40% of deaths in patients with immunodeficiency, and antiviral medications are limited by toxicities and resistance. Restoration of T-cell immunity by adoptive immunotherapy could provide lasting control of targeted viral infections.

**Project Objective**

Phase 1/2 trial completed

**Major Proposed Activities**

- To determine the feasibility and safety of administering partially HLA-matched T-cells to treat persistent viral infections.
- To determine the antiviral efficacy of partially HLA-matched T-cells in immunodeficient patients with CMV, EBV, and/or adenoviral infection.
- To determine the effects of partially HLA-matched VST infusion on overall survival at 6 months and 12 months following infusion.

**Statement of Benefit to California:**

Hundreds of patients undergo hematopoietic stem cell transplantation annually in California, and viral infections pose a serious risk to these patients, as well as patients with primary immunodeficiency disorders. Antiviral therapy is often ineffective without restoration of T-cell immunity in this patient population. Rapid access to banked virus-specific T-cells, which may reconstitute T-cell immunity against these viruses, could be a lifesaving therapy for many of these patients.

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